Complete Summary

GUIDELINE TITLE

Refractive errors.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Ophthalmology Refractive Errors Panel. Refractive errors. San Francisco (CA): American Academy of Ophthalmology; 2002. 53 p. [297 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Refractive errors, including hyperopia, myopia, astigmatism, and presbyopia

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Treatment

CLINICAL SPECIALTY

Ophthalmology
Optometry

INTENDED USERS

Allied Health Personnel
Optometrists
Physicians

GUIDELINE OBJECTIVE(S)

To improve the visual acuity, visual function, and visual comfort in patients with a refractive error by correcting the refractive error when appropriate, by addressing the following goals:

- Determine the patient's visual needs.
- Identify and quantify any refractive errors.
- Discuss with the patient the nature of the refractive error, appropriate alternatives for correction, and the risks and benefits of each approach.
- Inform patients, especially those with high refractive errors, about the potential increased incidence of associated pathologic conditions.
- Correct symptomatic refractive errors with spectacles, contact lenses, or surgery as desired by the informed patient and as deemed appropriate by the physician.
- Provide the patient with follow-up care and management of any side effects or complications resulting from the correction provided.

TARGET POPULATION

Individuals who are beyond the amblyogenic age and have refractive errors

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. History
2. Examination, including acuity measurement and refraction testing

Management

1. Spectacles
2. Contact lenses, including soft hydrogel, rigid gas-permeable, or silicone hydrogel lenses
3. Refractive surgery
    - Photorefractive keratectomy (PRK)
    - Laser in situ keratomileusis (LASIK)
    - Laser epithelial keratomileusis (LASEK)
    - Insertion of intrastromal corneal ring segments (ICRS)
    - Radial keratotomy (RK)
    - Thermal keratoplasty
4. Other procedures (mostly investigational or rarely performed in the United States)
    - Clear lens extraction
    - Phakic intraocular lens implantation
    - Intracorneal inlays
    - Automated lamellar keratoplasty

    - Epikeratoplasty
    - Hexagonal keratotomy
    - Keratophakia
5. Photorefractive astigmatic keratectomy (PARK)
6. Astigmatic keratotomy (AK)
7. Surgical correction of presbyopia
    - Monovision
    - Multifocal photoablation
    - Anterior ciliary sclerotomy
    - Scleral expansion bands
    - Multifocal and accommodating intraocular lens
8. Counseling and referral

MAJOR OUTCOMES CONSIDERED

- Visual function (visual acuity) following correction of refractive errors
- Visual comfort and patient satisfaction following correction of refractive errors
- Complications of contact lenses and refractive surgery

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

In the process of updating and revising the original guideline, a detailed literature search of articles in the English language was conducted on the subject of refractive error for the years 1996 to September 2001.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Strength of Evidence Ratings

Level I: Includes evidence obtained from at least one properly conducted, well-designed randomized controlled trial. It could include meta-analyses of randomized controlled trials.

Level II: Includes evidence obtained from the following:

- Well-designed controlled trials without randomization
- Well-designed cohort or case-control analytic studies, preferably from more than one center
- Multiple-time series with or without the intervention

Level III: Includes evidence obtained from one of the following:

- Descriptive studies
- Case reports
- Reports of expert committees/organization
- Expert opinion (e.g., preferred practice patterns panel consensus)

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The results of the literature search were reviewed by the Refractive Errors Panel and used to prepare the recommendations, which they rated in two ways.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The results of a literature search on the subject of refractive errors were reviewed by the Refractive Errors Panel and used to prepare the recommendations, which they rated in two ways. The panel first rated each recommendation according to its importance to the care process. This "importance to the care process" rating represents care that the panel thought would improve the quality of the patient´s care in a meaningful way. The panel also rated each recommendation on the strength of the evidence in the available literature to support the recommendation made.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Ratings of importance to care process

Level A, most important
Level B, moderately important
Level C, relevant, but not critical

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

These guidelines were reviewed by Council and approved by the Board of Trustees of the American Academy of Ophthalmology (September 2002). All Preferred Practice Patterns are reviewed by their parent panel annually or earlier if developments warrant and updated accordingly.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Specific recommendations are followed by a rating indicating level of importance to the care process (A-C) and a strength of evidence rating (I-III), both of which are defined at the end of the "Major Recommendations" field.

Diagnosis

The evaluation of refractive errors requires an assessment of both the refractive status of the eye and the patient´s symptoms and visual needs. [A:III]

History

The history usually identifies symptoms suggestive of a refractive error and the level of the patient´s visual difficulties. [A:III]

Examination

The main components of the examination consist of measuring acuity and refractive error. [A:III]

Measuring Acuity

Distance acuity should be measured separately for each eye with current correction. [A:III]

Refraction

Distance refraction should be performed with accommodation relaxed. [B:III]
Near vision should be measured in each eye prior to cycloplegia for patients with high hyperopia, presbyopia, or complaints about near vision. [B:III]

Excellent acuity does not exclude serious eye disease; all patients should have a comprehensive medical eye evaluation at the recommended intervals. [A:III]

Management

Detailed recommendations for management are in the original guideline document.

Patients with low refractive errors may not require correction; small changes in refractive corrections in asymptomatic patients are generally not recommended. [A:III] Spectacles should be considered before contact lenses or refractive surgery. [A:III]

Spectacles

A patient´s spectacles and refraction should be evaluated whenever visual symptoms develop. [A:III]

Safety glasses or eye protectors are strongly recommended for individuals involved in certain sports and hazardous activities in which there is risk of flying particles (e.g., using hammers, saws, weed trimmers). [A:III] They are also recommended for all individuals with good vision in only one eye. [A:III]

Contact Lenses

Patients fitted with a contact lens should be made aware that using contact lenses can be associated with the development of ocular problems, including microbial corneal ulcers that may be vision threatening. [A:II] The increased risk of ulcerative keratitis with extended contact lens wear should be discussed with patients who are considering this modality of vision correction. [A:I] A patient wearing contact lenses should be instructed to remove them immediately if either eye becomes red, irritated or painful, and to seek medical care if these symptoms do not promptly resolve with lens removal or if visual acuity decreases. [A:III] Patients considering overnight wear should be apprised of their responsibilities and the increased risks of overnight wear compared to daily wear prior to being fitted with these lenses. [A:III]

Follow-up Evaluations

Initial contact lens fitting should include follow-up examinations to assess visual acuity, comfort, and lens fit before the fitting process is considered completed. [A:III] First-time daily-wear or extended-wear contact lens users should be checked soon after the lenses are initially dispensed. [A:III] Experienced contact lens users should generally be examined annually. [A:III]

Refractive Surgery

A comprehensive medical eye evaluation should be performed prior to any refractive surgery procedure. [A:III] The refractive surgery examination should also include the following elements: [A:III]

- Visual acuity without correction
- Computerized corneal topography
- Corneal pachymetry
- Measurement of pupil size in low-light conditions
- Evaluation of tear film

- Cycloplegic refraction

Follow-up Evaluations

For photorefractive keratectomy (PRK) patients, postoperative examination including slit-lamp biomicroscopy of the cornea is advisable on the day following surgery and every two to three days thereafter until the epithelium is healed. [A:III] For laser in situ keratomileusis (LASIK) patients, postoperative examination is mandatory on the first day following surgery. Then patients can be examined approximately one week following surgery and thereafter as appropriate. [A:III]

Provider and Setting

Patients with refractive errors should be examined and evaluated for treatment by an ophthalmologist or an optometrist. [A:III] Surgical treatment of refractive errors, including excimer laser surgery, should be performed only by an appropriately trained ophthalmologist. [A:III] Postoperative management is integral to the outcome of any surgical procedure and is the responsibility of the operating surgeon. [A:III]

Counseling/Referral

Any decisions regarding surgical correction of a refractive error should be made by an informed patient and an ophthalmologist familiar with refractive surgery. [A:III] Information and discussion about the planned procedure should be available sufficiently in advance of the proposed surgical date so that the patient can carefully consider the risks, benefits, and alternatives to the procedure. [A:III] The patient should be informed of the potential risks, benefits, and alternatives to and among the different keratorefractive procedures prior to surgery. [A:III] The advantages and disadvantages of same day bilateral keratorefractive surgery versus sequential surgery should be reviewed. There also should be a discussion of postoperative care plans (setting of care, providers of care). Because vision might be poor for some time after photorefractive keratectomy, bilateral same day surgery should be approached with caution, and the patient informed that activities such as driving might not be possible for weeks. [A:III] The informed consent process should be documented, and the patient should be given an opportunity to have all questions answered prior to surgery. [A:III]

Definitions

Importance to the care process:

Level A: defined as most important

Level B: defined as moderately important

Level C: defined as relevant but not critical

Strength of evidence:

Level I: Includes evidence obtained from at least one properly conducted, well-designed randomized controlled trial. It could include meta-analyses of randomized controlled trials.

Level II: Includes evidence obtained from the following:

- Well-designed controlled trials without randomization
- Well-designed cohort or case-control analytic studies, preferably from more than one center
- Multiple-time series with or without the intervention

Level III: Includes evidence obtained from one of the following:

- Descriptive studies
- Case reports
- Reports of expert committees/organization
- Expert opinion (e.g., preferred practice patterns panel consensus)

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- The major reasons for treating refractive errors are to improve a patient´s visual acuity, visual function, and visual comfort. It may be desirable to correct a very small error in one patient, while another may function well with no ill effects when the refractive error is not corrected. Other reasons for treatment include enhancing binocular vision (e.g., for driver safety) and decreasing strabismus (e.g., accommodative esotropia).
- Many patients who use contact lenses note better field of vision, greater comfort, and/or an improved quality of vision.
- Photorefractive keratectomy reduces myopia; it is most predictable for low to moderate myopia and less predictable for high myopia. Published reports document that from 67% to 98% of patients have achieved 20/40 uncorrected vision, and 48% to 86% have achieved 20/20 uncorrected vision.
- Laser in situ keratomileusis (LASIK) is reported to reduce refractive errors, including myopia and astigmatism. Low to moderate errors can be corrected with a higher degree of predictability than higher errors with minimal loss of best corrected visual acuity (BCVA). Based on recent series, 79% to 93.5% of patients achieved uncorrected vision of 20/20 or better for myopia of less

than 6 D, and more than 92% achieved uncorrected vision of at least 20/40. For patients with preoperative refractive errors ranging from 6 to 12 D, uncorrected visual acuity of 20/20 was achieved in 26% to 57% of patients, while uncorrected acuity of 20/40 was achieved in 56% to 94%. Laser in situ keratomileusis retreatment often reduces residual refractive error.

- Advantages of clear lens extraction include rapid rehabilitation and predictability of refractive outcome.
- Advantages of phakic intraocular lens implantation include rapid visual recovery, stability of achieved correction, and the ability to correct high myopic refractive errors.
- Laser in situ keratomileusis has been used to correct low and moderate hyperopia with satisfactory predictability.
- In the Food and Drug Administration (FDA) trials of laser thermokeratoplasty (LTK), about 80% of eyes were corrected to within 0.50 D of emmetropia with no reported loss of best corrected visual acuity.
- One retrospective study of laser in situ keratomileusis for simple myopic, mixed, and simple hyperopic astigmatism demonstrated postoperative visual acuity of 20/40 or better in 85% of eyes at 3 months and within 1 D of intended correction in 95% of eyes.
- Zonal-progressive multifocal intraocular lenses have been shown to reduce presbyopic symptoms and spectacle dependence in two large prospective fellow-eye comparative studies, one of which was randomized and double masked.

Subgroups Most Likely to Benefit:

Some patients achieve optimal visual function only with contact lenses. These may include patients with high refractive errors, symptomatic anisometropia or aniseikonia, or an irregular corneal surface or shape.

POTENTIAL HARMS

- Complications of contact lens use: The most serious risk of contact lens use is the development of microbial keratitis, which can lead to visual loss even if properly treated. Other complications include tarsal papillary conjunctivitis, bulbar conjunctival changes, epithelial keratopathy, corneal neovascularization, nonmicrobial corneal infiltrates, and corneal warpage. Endothelial changes can also occur, including polymegathism, pleomorphism, and, rarely, reduction of endothelial cell density. Progressive corneal thinning of the epithelium and stroma during lens wear has also been reported.
- Complications of Radial Keratotomy: Potential complications include glare, starbursts, fluctuation of vision, regression or progression of refractive effect, anterior chamber perforation, and infectious keratitis.
- Complications of Photorefractive Keratectomy (PRK) and Laser In Situ Keratomileusis (LASIK):

  Optical side effects and complications include:

  - Symptomatic undercorrection or overcorrection
  - Regression of effect
  - Loss of best corrected visual acuity (BCVA)

- Visual aberrations, including transient or permanent glare or starburst/halo effect, especially at night
- Decreased contrast sensitivity
- Induced regular or irregular astigmatism, induced anisometropia, and premature need for reading correction.

Medical side effects and complications include:

- Corneal haze or scarring (early or delayed onset)
- Corneal infiltrates, ulceration, melting, or perforation (sterile or microbial)
- Keratectasia (progressive corneal steepening)
- Development or exacerbation of dry eye symptoms
- Decreased corneal sensitivity
- Recurrent corneal erosion
- Reactivation of herpes simplex keratitis
- Corticosteroid-induced complications (e.g., ocular hypertension, glaucoma, cataract)
- Ptosis
- Artifactual reduction of measured intraocular pressure (IOP) (due to corneal thinning)
- Posterior segment conditions (e.g., retinal breaks, detachments). Although there are case reports of retinal abnormalities that have been recognized following photorefractive keratectomy and laser in situ keratomileusis, it is unclear if the incidence would be any different than in a comparable myopic population.
- Interface inflammation and postoperative infection can also occur with laser in situ keratomileusis.

- Side effects and complications of the intracorneal ring segment (ICRS) procedure include fluctuation of vision; undercorrection; induced regular or irregular astigmatism; glare; haloes; anterior or posterior corneal perforation; segment malposition, migration or extrusion; pain; infectious keratitis; and lamellar channel deposits.
- Disadvantages of clear lens extraction include loss of accommodation and the inherent complications of an intraocular procedure, including endophthalmitis and the increased risk of retinal detachment, particularly in patients with high axial myopia.
- Potential complications of phakic intraocular lens implantation include endophthalmitis, endothelial cell loss, chronic iridocyclitis, cataract formation, iris distortion, pigment dispersion, glaucoma, and intraocular lens (IOL) dislocation.
- Complications of automated lamellar keratoplasty include irregular astigmatism, thin flaps, free or displaced caps, anterior chamber perforation, interface opacities, infectious keratitis, and epithelial ingrowth.
- Complications of epikeratoplasty include poor wound healing, irregular astigmatism, interface haze, lenticule necrosis, and infectious keratitis.
- Concerns about photorefractive keratectomy for hyperopia (H-PRK) include the large epithelial defect and the longer time period required for re-epithelialization compared with myopic photorefractive keratectomy; this results in a longer period of discomfort, slower visual recovery, and an increase in the risk of infection. Although overall corneal haze was generally mild, there have been more significant haze problems in the midperipheral

ring, usually sparing the visual axis. There is a slower recovery of best corrected visual acuity in photorefractive keratectomy for hyperopia than in myopic photorefractive keratectomy.

- Thermal keratoplasty, noncontact technique: Initial overcorrection is expected and built in to the treatment algorithms. Disadvantages include this early overcorrection, the inability to treat astigmatism, the possibility of inducing astigmatism, and possible corneal scarring (peripheral to the visual axis).
- Thermal keratoplasty, contact technique: Disadvantages include early overcorrection, the inability to treat astigmatism, and the possibility of inducing astigmatism.
- Complications of photorefractive astigmatic keratectomy: Optical side effects and complications include symptoms of glare and ghosting in low-light conditions can occur in eyes that have undergone astigmatic laser treatment. In part, this may result from the pupil diameter in low-light conditions being larger than the short axis of ablation. Other complications include incomplete astigmatic correction or induced astigmatism. Medical side effects and complications: The medical side effects and complications of photorefractive keratectomy and laser in situ keratomileusis for astigmatism are the same as for myopia.
- Complications of astigmatic keratotomy include anterior chamber perforation, regression or progression of effect, wound gape or dehiscence, infectious keratitis, irregular astigmatism, and fibrous scarring.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contact Lens: Relative Contraindications

The use of contact lenses to correct refractive errors may not be advisable when there are significant eyelid, tear film, or ocular surface abnormalities related to keratoconjunctivitis sicca, blepharoconjunctivitis, acne rosacea, conjunctival cicatrization, corneal exposure, neurotrophic keratitis, or other corneal abnormalities. Contact lenses may be inadvisable for monocular or functionally monocular patients. Other relative contraindications include inflammation of the anterior segment, presence of a filtering bleb, poor hygiene, certain environmental or work settings (e.g., dust, volatile chemicals), a history of contact-lens-related corneal complications, limited dexterity, or inability to understand the risks and responsibilities involved.

Monovision

Caution should be used in considering monovision in patients who have had previous strabismus surgery, phorias, or intermittent tropias, as these patients may develop diplopia postoperatively.

Photorefractive Keratectomy (PRK) and Laser In Situ Keratomileusis (LASIK) Contraindications

- Unstable refraction

- Certain abnormalities of the cornea (e.g., most cases of keratoconus or other corneal ectasias, thinning, edema, interstitial or neurotrophic keratitis, extensive vascularization)
- Abnormal corneal topography suggestive of keratoconus or other corneal ectasias (LASIK only)
- Insufficient corneal thickness for the proposed ablation depth
- Irregular astigmatism (e.g., corneal warpage)
- Visually significant cataract
- Uncontrolled glaucoma
- Uncontrolled external disease (e.g., blepharitis, dry eye, atopy/allergy)
- Uncontrolled connective tissue or autoimmune disease
- Unrealistic patient expectations
- Orbital, lid, or ocular anatomy that precludes proper function of the microkeratome (LASIK only)

Photorefractive Keratectomy and LASIK Relative Contraindications

- Functional monocularity
- Ocular conditions that limit visual function
- Overly steep or flat corneas
- Abnormal corneal topography suggestive of keratoconus or other corneal ectasias (photorefractive keratectomy only)
- Poor epithelial adherence, anterior basement membrane dystrophy, or recurrent erosion syndrome (LASIK only)
- Corneal stromal or endothelial dystrophies
- History of herpes simplex or zoster keratitis
- Dry eye syndrome
- Prior incisional or lamellar keratorefractive surgery
- Pupil diameter in dim illumination that is greater than the planned ablation diameter
- Glaucoma
- Poorly controlled diabetes mellitus or ocular complications of diabetes mellitus
- Pregnancy or lactation
- Connective tissue or autoimmune diseases, systemic immunosuppression
- Certain systemic medications (e.g., isotretinoin, amiodarone, sumatriptan, levonorgestrel implants, colchicine)
- Under 18 years of age (FDA labeling should be consulted for each laser)
- Significant occupational or recreational risk for corneal trauma (LASIK only)

QUALIFYING STATEMENTS

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- Preferred Practice Patterns provide guidance for the pattern of practice, not for the care of a particular individual. While they should generally meet the needs of most patients, they cannot possibly best meet the needs of all patients. Adherence to these Preferred Practice Patterns will not ensure a successful outcome in every situation. These practice patterns should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the best results. It may be necessary to approach different patients´ needs in different ways. The physician must make the ultimate judgment about the propriety of the care of a particular

patient in light of all of the circumstances presented by that patient. The American Academy of Ophthalmology is available to assist members in resolving ethical dilemmas that arise in the course of ophthalmic practice.
- Preferred Practice Patterns are not medical standards to be adhered to in all individual situations. The Academy specifically disclaims any and all liability for injury or other damages of any kind, from negligence or otherwise, for any and all claims that may arise out of the use of any recommendations or other information contained herein.
- Treatments have been reported that purport to prevent progression of refractive errors, particularly myopia. Evidence reported in the peer-reviewed literature, including recent randomized clinical trials, is currently insufficient to support a recommendation for intervention (see Appendix 2 of the original guideline document).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Academy of Ophthalmology Refractive Errors Panel. Refractive errors. San Francisco (CA): American Academy of Ophthalmology; 2002. 53 p. [297 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 Sep (revised 2002)

GUIDELINE DEVELOPER(S)

American Academy of Ophthalmology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Ophthalmology

GUIDELINE COMMITTEE

Refractive Errors Panel; Preferred Practice Patterns Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The following authors have received compensation within the past 3 years up to and including June 2002 for consulting services regarding the equipment, process, or product presented or competing equipment, process, or product presented:

Stephen D. McLeod, MD: Visiogen – contract payments for research performed, contribution to research or research funds, contribution to travel funds, reimbursement of travel expenses for periods of direct consultation.

Neal A. Sher, MD: VISX, Inc – Ad hoc consulting fees, reimbursement of travel expenses for periods of direct consultation.

Joanne Katz, ScD: CIBA, Bausch and Lomb, Foresight Technologies – Ad hoc consulting fees.

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previous version: Refractive errors. San Francisco (CA): American Academy of Ophthalmology (AAO); 1997 Sep. 41 p.

This document is valid for 5 years from the date released unless superseded by a revision. All Preferred Practice Patterns are reviewed by their parent panel annually or earlier if developments warrant.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Ophthalmology (AAO) Web site.

Print copies: Available from American Academy of Ophthalmology, P.O. Box 7424, San Francisco, CA 94120-7424; telephone, (415) 561-8540.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on December 1, 1998. The information was verified by the guideline developer on January 11, 1999. This summary was updated on March 12, 2003. The updated information was verified by the guideline developer on April 2, 2003.

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